Public Citizen

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Joan Claybrook, President

July 25, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20857

RE: Docket No. 2005D-0169

Dear Sir or Madam:

Since our founding in 1972, Public Citizen, a consumer organization with a membership of over 130,000 people, has been actively advocating for the distribution of Food and Drug Administration (FDA) approved drug information written specifically for consumers that will be distributed with each new and refill prescription and is based on a drug's professional product labeling or package insert. Numerous times over the past 30 years, we have submitted comments, petitions, and testimony on the unequivocal right and need for prescription drug consumers to have reliable access to objective, scientifically accurate, useful information about the drugs they are prescribed.

Public Citizen served as member of the Steering Committee that met in Washington, DC between September and December 1996, facilitated by the Keystone Center, to develop The Action Plan for the Provision of Useful Prescription Medicine Information. The Action Plan, or Keystone process as it is sometimes known, forms the basis for defining useful written drug information for consumers. It is the basis for the draft guidance about which the FDA is requesting public comment. The Action Plan was agreed to by private sector information vendors and accepted by Donna E. Shalala, Secretary of the Department of Health and Human Services, in 1996.

Since its origins in 1979, the process to provide the public with access to useful drug information has proceeded at a glacial pace. It has been hampered immeasurably by the consistent failure of private sector information vendors[1,2] to deliver useful drug information to the public. This failure discredits the professional trade groups representing pharmacy, medicine, and the pharmaceutical industry because they have long placed a dogmatic aversion for all regulation, particularly FDA regulation, of patient drug information before the public interest.

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[1] Svarstad, B. L. and D. C. Bultman, ``Evaluation of Written Prescription Information Provided in Community Pharmacies: An 8-State Study," interim report to HHS and FDA, December 1999, available on the Internet at http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/cder/calendar/meeting/rx2000/report1.htm

[2] Svarstad, B. L. and J. K. Mount, ``Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001," final report to HHS and FDA, December 2001, available on the Internet at http://www.fda.gov/cder/reports/prescriptionInfo/default.htm

This Draft Guidance on Useful Written Consumer Medication Information was written by the FDA to inform private sector information vendors of what will be expected in the next legislatively mandated survey of the quality of prescription drug information distributed to consumers by pharmacists, which is due in 2006. It seems incredible that the FDA found it necessary to write this document, as the commercial information vendors participated on the Keystone Steering Committee that developed The Action Plan criteria and have been well aware of these criteria since 1996. Nevertheless, the Draft Guidance does appear to accurately reflect the intent of Keystone Steering Committee, and we urge the FDA to apply this guidance to its letter.

Consumers are concerned that the FDA may once again capitulate to the private sector and lower the bar for assessing useful information as they did with the failed 2001 survey.[2] In a June 2002 Talk Paper, the FDA proclaimed the "… success of private sector patient information," and that the "overall usefulness was about 50 percent" for the information being distributed to the public.[3] These statements were made by the FDA despite the fact that the patient information leaflets for four commonly prescribed drugs surveyed failed to meet the minimum voluntary quality criteria outlined in The Action Plan.

The notion that information intended to warn consumers about preventable adverse drug reactions that could result in serious injury or death that, according to a nationwide study commissioned by the FDA, is only 50 percent useful[1] is a success is unfathomable.

Medication Guides are FDA approved drug information written for patients that may be required by the agency, through regulation, to be distributed with drugs that pose a serious and significant public health concern. Public Citizen estimates that there are now, or soon will be, about 75 drugs that are required to be dispensed with Medication Guides. This regulatory path is the track the FDA should have followed for the thousands of other FDA-approved drugs after the private sector vendors failed in 2001 to provide consumers with any useful drug information.

Sincerely,

Larry Sasich, Pharm.D., M.P.H.
Researcher

Sidney Wolfe, M.D.
Director
Public Citizen's Heath Research Group

[3] FDA Talk Paper: SUCCESS OF PRIVATE SECTOR PATIENT INFORMATION WITH PRESCRIPTION MEDICINES ASSESSED, June 18, 2002, available on the Internet at http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01153.html